

PATENT
Docket No.: 10546/57503

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : R. Fortier, et al.
SERIAL NO. : Continuation of 09/902,636, filed July 12, 2001
FILED : Herewith
FOR : SYSTEM, METHOD, AND APPARATUS FOR
ACCURATELY DEPLOYING PARTICULAR MEDICAL
APPLIANCES AT A TARGET SITE (as amended)
GROUP ART UNIT : 3732 (Anticipated)
EXAMINER : Eduardo C. Robert (Anticipated)

M.S. Patent Application
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PRELIMINARY AMENDMENT

Sir:

Prior to examination of this application, please enter the following amendments. The amendments are presented in the revised amendment format authorized by the Office of Patent Legal Administration by Notice dated January 31, 2003.

IN THE TITLE:

Please amend the Title as follows.

**SYSTEM, METHOD, AND APPARATUS FOR ACCURATELY DEPLOYING
PARTICULAR MEDICAL APPLIANCES AT A TARGET SITE**

IN THE SPECIFICATION:

Please amend the specification as follows.

Please amend the paragraph beginning at page 1, lines 6-8 as follows:

This application is a Continuation of Application Serial No. 09/902,636, filed July 12, 2001, which claims the benefit of U.S. Provisional Application Serial No. 60/226,901, filed August 23, 2000, and incorporates these ~~that~~ applications herein, in ~~its~~ their entirety, by reference.

Please amend the paragraph beginning at page 1, lines 18-25 as follows:

Medical procedures may be performed by a practitioner through direct contact and interface with a target site as well as through remote access to the target site via medical devices, such as endoscopes, which are designed to extend the practitioner's reach. By extending the practitioner's reach these devices allow some medical procedures, previously performed only through invasive procedures, to be performed through non-invasive methodologies. One drawback of these extension devices and remote access methodologies is that a practitioner may not be able to watch the procedure being performed and, thus, may not be able to visually determine if the procedure he is performing has been properly completed.

Please amend the paragraph beginning at page 1, lines 26-28 and page 2, 1-15 as follows:

For instance, when an endoscope is being used for the ligation of a polyp deep within a patient's body, the distal end of the endoscope, where the procedure is actually carried out, is not directly visible to the practitioner. Nevertheless, despite this handicap, the practitioner must first maneuver the distal end of the endoscope to the targeted polyp and then, in less sophisticated systems, must perform the procedure relying solely on his or her own tactile abilities. In one endoscopic ligation unit this process would involve pulling on a single string emerging from the proximal end of the endoscope until one of the several bands, around which the string was wrapped ~~around~~ at its distal end, was deployed. In this unit, if the string ~~was~~ is pulled too far,

more than one band may be deployed and, if the string ~~was~~ is not pulled far enough, a band may not be deployed at all. During its use, once the practitioner thought that a single band was deployed, but without positive confirmation, the practitioner would relocate the distal end of the endoscope to deploy another band or if the procedure was completed, retract the endoscope from the patient.

Please amend the paragraph beginning at page 3, lines 12 and 13 as follows:

Figure 1 is a side perspective view of a removeable string system containing a plurality of strings prior to its insertion into a body in accord with one embodiment of the present invention.

Please amend the paragraph beginning at page 6, lines 25-28 and page 7, lines 1-10 as follows:

Figure 5 is a side perspective view of an alternative embodiment of the present invention. In Figure 5 ~~a means 50 for affirmatively verifying that at medical appliance from a plurality of medical appliances, has been deployed can be seen~~ verifying the deployment of a medical appliance from a plurality of medical appliances can be seen. ~~This means~~ Means 50 may be attached to an endoscope as illustrated in Figure 6. ~~This means~~ Means 50 may contain a plunger 52, a body 56, a string 53, and a variable length string passageway 51 and may be used to deploy ligation bands or other medical appliances located at the distal end of an endoscope. ~~This means~~ Means 50 accomplishes this task by shortening or otherwise pulling on a string contained within the passageway 51 that is coupled to a plurality of deployable medical appliances at the distal end of the endoscope. This string is pulled or shortened by a specific predetermined distance by depressing one of the plungers 52 of the means 50. As the plunger 52 is depressed, the string 53 resident in the passageway 51 and coupled to anchoring point 57 will have its effective length shortened by the distance that it must now travel around the depressed plunger 52. Thus, by depressing the plunger 52, the string will be shortened and a ligation band or other device coupled to the string may be deployed by the medical device.

Please amend the paragraph beginning at page 7, lines 11-25 as follows:

A specific method of using the means 50 from Figure 5 may include coupling the body 56 to an endoscope and then ~~treading~~ threading a string 53 through the string passageway 51 and anchoring point 57. The distal end of the string 53 may then be threaded around each deployable medical appliance in sequential order. Then, as mentioned above, in order to deploy the medical appliance, the plunger 52 may be depressed, in order to draw the string 53 into the valley 58 associated with the plunger 53 thus altering the string's pathway and shortening its effective length. Consequently, when a plunger 52 is depressed, a medical appliance coupled to the string's distal end may be deployed from the distal end of the medical device. If a second medical appliance is to be deployed, a second plunger may be depressed while the first plunger is also depressed. Here, the effective length of the string will be twice shortened and the second medical appliance may be deployed. Likewise a third appliance may also be deployed by depressing the third plunger 52 while the first two are also depressed. The plungers in this embodiment may be depressed in any order to deploy the first, second, and the third medical appliances since the string is not bound underneath the depressed plungers but, is rather, able to slide back and forth underneath the depressed plunger.

Please amend the paragraphs beginning at page 8, lines 6-28 and page 9, lines 1-8 as follows:

An alternative embodiment of a means 70 for affirmatively verifying ~~that the deployment~~ of a specific medical appliance from a plurality of appliances ~~has been deployed 70~~, is illustrated in Figure 7. ~~This means~~ Means 70 may be placed at the distal end of an endoscope and may be used to pull a string a predetermined distance in order to deploy a ligation band in communication with the string from a ligation tip at the distal end of the endoscope. ~~This means~~ Means 70 may include a shaft 76, an opening 72, and a slidable handle 71 coupled to the shaft 76 and adapted to be slid over the shaft 76. The handle 71 may also contain several slots 78 that may be sized to secure a looped end 75 of a ~~string~~ string 701 that may be attached to a plurality of ligation bands at the distal end of the endoscope or other device. Consequently, as the handle 71 is incrementally advanced down the shaft 76 the string 701 may be pulled by that same

incremental distance as the handle 71 is slid.

Alternatively, in another embodiment, rather than having the string directly coupled to the ligating bands, a pulley system may be employed that adjusts or modifies the distance that handle 71 needs to be pulled before each ligation band is deployed. This pulley system or mechanical advantage system may increase the distance that the handle needs to be pulled or conversely decrease the distance that the handle needs to be pulled.

Also evident in Figure 7 are a plurality of stops 73, 74, and 77, and 702 that protrude ~~up~~ from the shaft 76 and may be sized to arrest the travel of the handle 71 as it slides down the body 76. These stops may be integrally formed with the shaft 76 and may be compressible or incompressible. The compressible stops 73 and 77, and 702 in this embodiment may be designed so that they may be depressed to allow the handle 71 to be slid over them and down the shaft from position to position as indicated by arrows 702 in Figure 7. Conversely, stop 74, which is fixed and incompressible in this embodiment, may act to prevent the handle 71 from sliding further down the body 76, thus acting as a block at the end of the handle 71. In addition, stops may also be used to arrest the travel of the handle 71 in the direction opposite to the arrows 702. An example of this type of stop is stop 79 which is shown preventing the handle 71 from sliding closer to opening 703 and obstructing the string 701 that protrudes from it. In this embodiment, as well as the embodiments discussed above, the shaft or body of the device may be made from rigid plastic, surgical grade metals, and other suitable materials.

Method System, method, and apparatus for deploying medical ~~appliance~~ device from a medical appliance is provided. While several embodiments of the present invention have been described above other embodiments within the spirit and scope of the present invention are also ~~plausible~~ possible.